REMARKS

Reconsideration is respectfully requested.

Entry of the above amendments is courteously requested in order to place all claims in this application in allowable condition and/or to place the non-allowed claims in better condition for consideration on appeal.

Claims 1 through 12, 33 through 35, and 37 through 39 remain in this application. Claims 13 through 32, 36, 40 and 41 have been cancelled. Claims 13 through 32 were previously withdrawn, and have been cancelled in this Amendment. Claims 42 and 43 have been added.

The Examiner's rejections will be considered in the order of their occurrence in the Office Action.

Parts 1 and 3 through 5 of the Office Action

Claims 1 through 6 and 33 through 41 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A).

Claims 7 through 9 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 4,903,707 A).

Claim 10 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Lake (US 3,766,910 A).

Claim 11 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to claims 1-6 above, further in view of Baudino (US 6,110,155 A).

Claim 12 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A), as applied to claim 11 above, further in view of McNeil et al. (US 4,828,546 A).

The rejections of parts 1 and 3 through 5 of the Office Action rely upon the allegedly obvious combination of selected elements of the Landy, Miller and Magram references. In general, the Landy reference discloses an intercranial pressure monitoring probe and the Miller reference teaches an apparatus for continuous monitoring of intercranial pressure. In both of these pressure monitoring apparatus, the retention of the pressure in the intercranial space is critical to the accurate measurement of the pressure in the intercranial space. In contrast, the Magram reference teaches a drain cannula apparatus mounted in the body in which the conduit simply carries fluids away from the brain, and the conduit is subjected to little if any pressure (and any significant back pressure could hinder or even block drainage through the conduit).

With this difference in function and purpose between Landy/Miller and Magram in mind, we turn first to the allegedly obvious modification of the Landy pressure monitoring probe by incorporating the sealing ridges 27 of Magram "to provide an integral mechanism for connecting the tubular portion to a tubular extension for remotely monitoring intercranial pressure, which is viewed as an art equivalent alternative to the t-connector disclosed by Landy et al.

It is submitted that one of ordinary skill in the art, considering the teaching of Landy, would not be motivated to look to the Magram reference and modify the Landy structure in the manner asserted in the Office Action. Initially, as noted generally above, the Landy apparatus is concerned with

the retention of the intercranial pressure in its tube, and the transfer of that pressure to the pressure transducer, and therefore needs to be able to prevent the escape of fluid or air from the tube.

Specifically, to this end of retaining the pressure for accurate pressure measurement, the Landy teaching employs a tube 51 between the t-connector 50 and the pressure transducer diaphragm 54 that is suitable for retaining the pressure without fluid or gas escaping or entering the lumen 12 of the tube 51. The Landy reference discloses at col. 5, lines 3 through 9 (emphasis added):

> To monitor the fluid pressure in lumen 12, a <u>low compliance, relatively heavy plastic tube</u> 51, is connected to conventional T-connector 50 and is thus fitted onto boss 21. Tube 51 includes an internal passage 52 for coupling fluid from the subarachnoid space immediately above brain 20 of the patient to face 53 of pressure monitoring diaphragm or transducer 54.

The use of a low compliance (e.g., a relatively low ability of an object to yield elastically when a force is applied), heavy plastic tube is not surprising, as any expansion of the tube wall in an outward direction would affect the volume of the lumen and thus influence the pressure reading of the pressure transducer diaphragm of Landy.

In contrast, the drain apparatus of Magram employs a tube that is formed of a very flexible wall that easily permits enlargement of the lumen of the tube. See, e.g., Magram at col. 5, lines 19 through 25:

> The tube typically is of a flexible, elastically deformable material. Inserting the nipple into the lumen causes the tube to stretch around the nipple. The elastic deformation creates a lap joint between the tube and the nipple. The lap joint provides a liquid tight seal and some radial tension which increases resistance of the tube to disconnect from the nipple.

In fact, the tube employed by Magram is so thin, flexible and elastic that the major function of the Magram apparatus is to clamp the tube onto the nipple so that the tube does not come off of the nipple.

Thus, while the Landy apparatus employs a minimally elastic, thick walled tube resistant to expansion for measuring intercranial pressure, the Magram apparatus employs a flexible and elastic tube with a wall that is easily stretched about a nipple and sealing ridges formed thereon for simply draining excess fluid from the brain.

It is therefore submitted that one of ordinary skill in the art, considering the Landy patent and the purpose for which it is intended, would not look to the Magram patent for an "art equivalent" means for mounting a tube on the Landy t-connector since the Magram teaching employs a highly flexible and elastic tube (whereas the tube of Landy has low compliance) that may be suitable for fitting over the sealing ridges of Magram nipple in a drainage system but would be unsuitable for systems such as Landy which need relatively low compliance tubing to accurately measure pressure in the intercranial space. In other words, it is submitted that one of ordinary skill in the art, considering the low compliance and thick walled tube of Landy would not look to the Magram system for a suitable retaining means as Magram teaches sealing ridges are useful for flexible and elastic tubes that can expand about a nipple.

Further, with respect to the allegedly obvious modification of the Landy apparatus with the lateral extensions of Miller, it is submitted that one of ordinary skill in the art, considering the teaching of Landy, would not be motivated to incorporate the Miller lateral extensions into the Landy probe as asserted in the Office Action.

One problem in the prior art noted by the Landy teaching is that the excessive protrusion of prior art probes from the skull of the patient can cause the probe to be knocked loose from the skull. See, e.g., Landy at col. 1, lines 58 through 63 (emphasis added):

> The screw must be attached to a stopcock, which when manipulated causes movement and loosening of the screw. The combination of the screw and stopcock produces a device which extends for a considerable distance above the scalp and is therefore easily jarred loose.

Therefore, one object of the Landy teaching is to minimize the profile of the installed pressure monitoring probe. See, e.g., Landy at column 3, line 28 (emphasis added):

> To maintain a low profile, the outer end of the probe is connected to the male end of a standard T-connector, rather than to a stopcock.

However, any attempt to modify the Landy probe by adding the lateral extensions of Miller to Landy would invariably increase the profile of the Landy probe in a manner that is undesirable to the Landy teaching. It is noted that the boss 21 of the Landy probe nests in a cavity 38 formed in the nut 33 during installation of the probe, and thus the addition of any lateral extensions would require the lengthening of the probe to accommodate the lateral extensions outside of the cavity of the nut, thereby increasing the profile of the probe in a manner undesirable to the objectives of the Landy patent. Landy teaches a removable wrench that drives the probe into the skull but is then removable from the probe to provide a low profile that is less likely to be jarred loose from the skull.

It is therefore submitted that one of ordinary skill in the art, considering the problems and objectives disclosed in Landy, would not be motivated by the Miller teaching to add lateral extensions to the Landy probe.

It is therefore submitted that the prior art, and especially the allegedly obvious combination of Landy, Miller and Magram set forth in the rejection of the Office Action, would not lead one skilled in the art to the applicant's invention as required by claims 1 and 6. Further, claims 2 through 5 and 33 through 35, which depend from claim 1, and claims 7 through 12 and 37 through 39, which depend from claim 6, also include the requirements

discussed above and therefore are also submitted to be in condition for allowance.

Withdrawal of the §103(a) rejection of claims 1 through 12 and 33 through 41 is therefore respectfully requested.

Parts 2 and 6 through 9 of the Office Action

Claims 1 through 6 and 33 through 41 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A).

Claims 7 through 9 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to claims 1-6 above, further in view of Knute (US 4,903,707 A).

Claim 10 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to claims 1-6 above, further in view of Lake (US 3,766,910 A).

Claim 11 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to claims 1-6 above, further in view of Baudino (US 6,110,155 A).

Claim 12 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A) as applied to claim 11 above, further in view of McNeil et al. (US 4,828,546 A).

The rejections of parts 2 and 6 through 9 of the Office Action rely upon the allegedly obvious combination of selected elements of the Miller

and Magram references. As noted above, the Miller reference teaches a intercranial pressure monitoring apparatus, and a probe 40 extends through a subarachnoid bolt 11 so that a sensing end of the probe is actually positioned in, or very close to, the intercranial area of the patient. From the rearward end of the probe 40 extend a plurality of wires, as the sensing of the intercranial pressure occurs at the forward end of the probe 40 and therefore these is no need to attach a tube or other conduit to the subarachnoid bolt 11 in order to transfer a pressure condition from the intercranial space to a remote pressure transducer, as the pressure transducer is located in the intercranial space or in the subarachnoid bolt 11. The Miller reference teaches that the monitoring of intercranial parameters by the probe of Miller needs to be conducted in the intercranial space of the patient, and cannot be performed remote from the intercranial space.

Further, the locking cap 13 constricting ring 15 and O-ring a7 help to secure the probe in the subarachnoid bolt 11. See, e.g., Miller at col. 8, lines 41 through 55 (emphasis added):

> Elements of the intracranial access system 20 include a subarachnoid bolt 11, a locking cap 13, a constricting ring 15, and an O-ring 17. The subarachnoid bolt 11 is a disposable skull mounting device having a lumen or passage with openings which provide intracranial access when it screwed into the cranium. <u>When the combined probe 40 passes through the elements of the intracranial access system 20 and the locking cap 13 is securely screwed onto the subarachnoid bolt 11, the constricting ring 15, which includes a bore, and the O-ring 17 cooperate to secure the probe and provide an airtight seal around the probe for intracranial sterility and stability, as well as to prevent the introduction of light artifact within the locus of measurement.</u> Such a coupling member is analagous to what is sometimes referred to as a compression fitting.

It is submitted that one of ordinary skill in the art would not abandon this structure for securing the Miller probe to the subarachnoid bolt 11 for the tube-securing ridges of Magram, as these ridges would be unsuitable for securing the probe of Miller to the subarachnoid bolt.

It is therefore submitted that one of ordinary skill in the art, considering the Miller teaching, would not look to the Magram teaching to modify the Miller apparatus for drainage or remote sensing on intercranial conditions. It is noted that the Landy apparatus is simply directed to only monitoring intercranial pressure, while the Miller reference teaches that it is highly beneficial to monitor several parameters measurable in the intercranial space.

Withdrawal of the §103(a) rejection of claims 1 through 12 and 33 through 41 is therefore respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, early reconsideration and allowance of this application are most courteously solicited.

Respectfully submitted,

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